James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
Telephone: 602.382.6000
Facsimile: 602.382.6070
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
Telephone: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS OF ROBERT O. RITCHIE, PH.D.

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

The Plaintiffs' Response[1] highlights Dr. Ritchie's professional history and argues that his background as an engineer qualifies him to testify about filter complication failure

[1] Plaintiffs filed a separate Omnibus Statement Of Law And Generally-Applicable Arguments In Opposition To Bard's Motions To Exclude Plaintiffs' Experts Under Rule 702 And Daubert (Doc. 7799). Plaintiffs' Omnibus Statement is not directed at any specific Daubert motion Bard filed. As such, Bard does not respond to the Omnibus

rates, the adequacy of Bard's filter testing, his "vicious circle" theory, and that the Simon Nitinol Filter ("SNF") is a safer alternative design. These opinions, however, are not based on any scientific methodology, and they rely upon the work of other experts without any independent verification, thus, they are unreliable, will not assist the trier-of-fact, and should be excluded.

A. Dr. Ritchie Is Not Qualified To Comment on or Refer in Any Way to Failure Rates or Relative Rates of Complications.

Dr. Ritchie intends to provide opinions in this litigation that Bard retrievable filters have high and unacceptable complication rates. (Ex. B to Mot., Ritchie 3/2/17 Rule 26 Report, at 2, 45, 105); (Ex. C to Mot., Ritchie 5/12/17 Rule 26 Rebuttal Report, at 5); Ex. A to Mot., Ritchie Dep. Tr., 133:18-25, June 9, 2017.) Plaintiffs argue that Dr. Ritchie may opine on the issue of rates, as a materials engineer, because he relies on published literature and the "relative risks" calculated by Plaintiffs' expert, Dr. Betensky. (Pls. Br. (Doc. 7807), at 3:23-26.) Plaintiffs do not suggest that Dr. Ritchie is a medical doctor, statistician, or an epidemiologist experienced in interpreting medical data and medical literature. Dr. Ritchie himself admits he does not have those qualifications. (Ex. A to Mot., Ritchie Dep. Tr., 152:14-21, June 9, 2017); (Ex. D to Mot., Ritchie Dep. Tr., 39:16-17; 69:11-13, May 23, 2011.) He has demonstrated no other qualifications that would permit him to assess the reliability or applicability of medical literature, or Dr. Betensky's analysis, to support these opinions. In such circumstances, courts have limited the scope of an expert's opinions where they venture into areas outside the scope of their qualifications. *See e.g. Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (finding that a physician who had significant clinical experience with the medical device at issue went "well beyond the 'reasonable confines' of his clinical expertise" when offering opinions regarding biomedical engineering and material science, and that therefore the physician was not qualified to offer such opinions); *See In re Silicone Breast*

Statement but instead will address any necessary issues in the context of its individual Daubert replies.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Implants Litig., 318 F.Supp.2d 879, 902 (C.D. Cal. 2004) (excluding opinions about the defendant's failure to conduct tests proffered by the plaintiff's expert, who had worked in quality control for a pharmaceutical company, published papers about medical devices, and holds patents on medical devices, on the grounds that such experience is insufficient foundational knowledge for offering opinions on testing); *Kruger v. Johnson & Johnson Prof'l, Inc.*, 160 F. Supp. 2d 1026, 1031 (S.D. Iowa 2001) (finding that a metallurgist was unqualified to offer design opinions regarding bone screws where he had no experience in the design of medical implants or any other medical devices); *In re: Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1243-44 (D. Colo. 1998) (excluding design opinions of a scientist who held a Ph.D. in physical chemistry because being a chemist did not automatically qualify the witness on design issues when he lacked training and experience concerning design of breast implants). The Plaintiffs make no effort to distinguish this body of cases.

Plaintiffs simply argue that as a materials engineer, he may rely on published literature and Dr. Betensky's analysis in opining that Bard filter complication rates are unacceptably high. However, not only is this methodology employed by Dr. Ritchie insufficient to make his opinion reliable, it is tantamount to no methodology at all. Thus, these opinions by Dr. Ritchie should be excluded. *Salinas v. Amteck of Ky., Inc.*, 682 F. Supp. 2d 1022, 1030 (N.D. Cal. 2010) (in a case involving an allegedly defective scissor lift, excluding plaintiff's expert because "the evidence does no[t] reflect that he employed a methodology that would allow him to opine as an expert, as he testified that he never inspected the subject scissor lift."). Dr. Ritchie referenced a few, among the many, published studies on IVC filters, for example the Nicholson study, in support of his opinion that Bard filters have "high rates". (Ex. A to Mot., Ritchie Dep. Tr., 134:6 to 135:9, June 9, 2017.) Dr. Ritchie's lack of rigorous methodology is demonstrated by the fact that he does not even acknowledge the flaws in the Nicholson study admitted to in sworn testimony given by the author, or the publication of the correction to the study. (Nicholson, *Correction to Article About Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters*, Arch. Intern. Med. 972 (June 2012),

attached hereto as Exhibit G.) In that regard, Dr. Ritchie nevertheless acknowledges that results reported in certain published literature may be overstated because they are "small studies." (Ex. A to Mot., Ritchie Dep. Tr., 134:6 to 135:9, June 9, 2017.) Dr. Ritchie even admits he has not done an exhaustive review or analysis of the published literature. (*Id*. at 137:18 to 138:13.) He fails to demonstrate in any way what his process was in reviewing published literature that allows him to conclude that Bard filters have "high rates." At best, he merely echoes what selected published papers report, without having the qualifications or experience to provide a reliable analysis on what those reports actually show.

Dr. Ritchie's other methodology used to support his "high rates" opinion is his reliance on Dr. Betensky's analysis. However, his characterization of her opinion is not what Dr. Betensky concluded at all. Dr. Betensky does not opine in her report that Bard rates are "high" and she certainly does not opine that any rates are "unacceptably high" relative to other retrievable filters. Instead, Dr. Betensky merely calculated a "reporting risk ratio," ("RRR") which did nothing more than compare the proportions of anecdotal adverse event reports for the various retrievable filters over sales to the proportions of anecdotal adverse event reports for the Simon Nitinol Filter over its sales.[2] Dr. Betensky emphasized that "the qualifier 'reported' is important and that's indicating that the data are coming from reports, and are not being derived from a beautifully run and designed experiment like a clinical trial, in which there's perfect follow-up and in which it's really a true experiment. So the 'reporting' qualifier is there to say and to suggest that these are numbers that are reported. These are based on reports." (Betensky Austin Dep. Tr.,

[2] In addition, if Dr. Betensky's analysis of comparative complication rates between SNF and Bard retrievable filters were based on valid data – and it is not -- the underlying SNF data Dr. Betensky used is flawed. Specifically, she used sales and adverse event information beginning in the year 2000, even though she was aware that "the SNF was launched in 1990." (Ex. E, Betensky 1/27/17 Rule 26 Report, at 13.) She, therefore, omitted the first ten years of adverse event reports and sales data from her analysis of the SNF. (Betensky MDL Dep. Tr., 125:20 to 126:2, June 23, 2017, attached hereto as Exhibit H.) When questioned about this, Dr. Betensky conceded that she would have used the adverse event data for the first 10 years of the SNF if she had it, and that the failure to factor it into her analysis affects the results. (*Id*. at 122:1-13; 189:21-22.)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

60:12-20, July 26, 2016, attached hereto as Exhibit I.) Because of the inherent limitations in the data that she considered, Dr. Betensky described her RRR as a "crude estimate of risk." (*Id.* at 106:20-25.) Indeed, by her own admission, Dr. Betensky's RRR "could be an overestimate or it could be an underestimate" of risk. (*Id.* 62:14-19.)

Dr. Ritchie is not qualified to give opinions in this case regarding Bard's filter complications rates. He is not qualified to characterize them as "high" or "unacceptably high" rates. The methodology Dr. Ritchie uses to reach this opinion is insufficient to insure that the opinions are reliable. Thus, these opinions of Dr. Ritchie should be excluded.

B. Dr. Ritchie's "Vicious Circle" Opinion Is Unreliable.

Dr. Ritchie's "vicious circle" opinion (that occurrence of one complication in a filter leads to another) is unreliable because it is not based on sufficient data, or any independently verified work. Dr. Ritchie admitted he cannot say that it is more probable than not that one failure mode occurring in a filter will trigger another failure mode, (Ex. A to Mot., Ritchie Dep. Tr., 95:6:18-101:24, June 9, 2017.) Dr. Ritchie testified that the vicious circle of complications is "intuitively obvious" to him (*Id*. at 88:8-21; 88:22- 89:2) and he admits that determining whether one complication precedes another "is sort of almost an impossible question to answer." (*Id*. at 97:8-10.) Dr. Ritchie provided no step-by-step methodology that he used to determine that one complication leads to another. If he had any methodology, it was merely relying on Dr. McMeeking's calculations and Dr. Ritchie's own intuition. Reliance on Dr. McMeeking's calculations is insufficient to make this opinion of Dr. Ritchie reliable (see discussion, *infra*). As for his use of intuition, that amounts to the use of *ipse dixit* in place of methodology, a tactic that *Daubert* and its progeny make impermissible. *See e.g. Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (stating"[w]e've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.").

The Plaintiffs (but not Dr. Ritchie himself) then cite to a short excerpt of testimony

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

from Christopher Ganser, a Bard corporate witness, and to one published medical study, (the Binkert study) as support for Dr. Ritchie's vicious circle opinion. When asked if tilting *could* put a patient at an increased risk of perforations, of migrations, of fracture, and of the device not working for its intended purpose, Mr. Ganser testified "the tilting *could* contribute to that." (Pls. Br. at 7:1-11). Mr. Ganser's conditional testimony is far from concrete evidence of the vicious circle Dr. Ritchie postulates. Dr. Ritchie has not established what qualifications Mr. Ganser had, or what information he utilized, to give this qualified statement, and he does not show what scientific methodology, if any, was behind Mr. Ganser's statement. The Binkert article, a study of the technical success and safety of G2 filter retrievals in 100 patients, concluded in part that "[t]he study data show a significant relationship between tilt or [sic] more than 15° and migration ($P < .001$); however, there is no statistical evidence that either migration or tilt is related to penetration." (Binkert, et al., *Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study*, 20 J. of Vascular and Interventional Radiology, 1449, 1452 (2009), attached hereto as Exhibit J.) Without more, this study among 100 subjects is not sufficient proof of the vicious circle, especially when the authors specifically state there is no statistical evidence from their study to show that migration or tilt are related to penetration.

Dr. Ritchie also refers to Dr. McMeeking's analysis in these cases as support for his own opinions on the "vicious circle." (Ex. A to Mot., Ritchie Dep. Tr., 84:1 to 91:8, June 9, 2017.) However, as Bard noted in its Motion, Dr. Ritchie testified that he has not verified any of Dr. McMeeking's calculations, and that he defers to Dr. McMeeking on the results of those and how they may support this theory. (*Id.* at 101:25-107:1.) Notwithstanding Bard's challenges to the reliability and admissibility of Dr. McMeeking's separate analyses, even if one assumes Dr. McMeeking's analyses lend some support to Dr. Ritchie's vicious circle theory, an expert's primary reliance on the opinions of other experts raises serious reliability questions. Expert opinions that rely on other expert opinions are admissible as long as the expert does not merely act as a conduit

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

for the other expert's opinion unless the record shows that the other expert independently evaluated the evidence supporting the other expert's opinion. *In re Toyota Motor Corp. Unintended Acceleration Mktg. Sales Practices, and Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013) (emphasis added). *See also Fosmire v. Progressive Max Ins. Co.*, 277 F.R.D. 625, 629 (W.D. Wash.2011) ("Dr. Polissar's expert report is deficient in several ways. First, although his opinions are based on Dr. Siskin's data and methodology, there is nothing in the record to indicate that Dr. Polissar has tested Dr. Siskin's underlying data to ensure its reliability or that Dr. Polissar even has access to Dr. Siskin's underlying data"); *In re Imperial Credit Indus., Inc. Secs. Litig.*, 252 F. Supp. 2d 1005, 1012 (C.D. Cal. 2003) ("The rules do not permit an expert to rely upon excerpts from opinions developed by another expert for the purposes of litigation"); *see also Am. Key Corp. v. Cole Nat'l Corp.*, 762 F.2d 1569, 1580 (11th Cir. 1985) ("Expert opinions ordinarily cannot be based upon the opinions of others whether those opinions are in evidence or not").

Dr. Ritchie's opinions on vicious circle are unreliable because he did not employ any scientific method to support his theory, and instead relies on his background as an engineer, a conditional statement from a Bard employee, a single piece of medical literature without consideration of the evidence about the study's flaws, and the conclusions of Dr. McMeeking without independently verifying them.

C. Dr. Ritchie's Criticisms of Bard's Testing Is Unreliable.

Bard obviously disagrees with Dr. Ritchie's assertion that Bard's testing was flawed because, according to his claim, it failed to reveal the fractures and complications that ultimately manifested in actual patients. (Pls. Br. at 8:19-22.) Even if Dr. Ritchie is qualified to opine on Bard's testing, the complete absence of any engineering or scientific methodology to support his opinions that the testing was insufficient renders his opinion unreliable. (Ex. A to Mot., Ritchie Dep. Tr. Supp., at 36:20-37:8; 118:15-120:9; 161:4-162:3, June 9, 2017.) Indeed, courts have excluded opinions made by learned individuals who failed to employ sufficient methodology to arrive at their opinions. *See e.g.*

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Medtronic, Inc. v. Boston Scientific Corp., No. 99-1035 (RHK/FLN), 2002 U.S. Dist. LEXIS 28355, **51-56 (D. Minn. Aug. 8, 2002) (excluding as unreliable a mechanical engineer's testimony that a stent was defectively designed because, although the engineer relied on others' testing of the stent, the engineer did not test his hypothesis on the stents at issue, noting that "failure to test or validate his hypothesis, and his apparent departure from the level of intellectual rigor that characterizes his work in his usual professional practice, render his proposed opinion testimony . . . inadmissible under Rule 702"); *Salinas v. Amteck of Ky., Inc.*, 682 F. Supp. 2d 1022, 1030 (N.D. Cal. 2010) (in a case involving an allegedly defective scissor lift, excluding plaintiff's expert because "the evidence does no[t] reflect that he employed a methodology that would allow him to opine as an expert, as he testified that he never inspected the subject scissor lift"); *Harrison v. Howmedica Osteomedics Corp.*, No. CIV 06-0745 PHX RCB, 2008 U.S. Dist. LEXIS 26197, **40-44 (D. Ariz. Mar. 31, 2008) (finding that a metallurgical engineer's failure to test an orthopedic nail and the alternative designs about which he opined weighed against a finding of reliability).

If, as the Plaintiffs argue "it is self-evident that any testing of a product should be designed to detect complications that occur during real world use," (Pls. Br. at 8:22-24), then Dr. Ritchie's opinion on the matter is not necessary because the Plaintiffs purport that, even in the complicated world of medical device design, this proposition is essentially "common sense." *See e.g. Fujifilm Corp. v. Motorola Mobility LLC*, No. 12-cv-03587-WHO, 2015 WL 757575, at *27 (N.D. Cal. Feb. 20, 2015) (striking portions of expert report that were "replete with observations and inferences that jurors are perfectly capable of making for themselves without [expert] assistance," even where such sections were "technical in nature"); *Miller v. Stryker Instruments*, No. CV 09-813-PHX-SRB, 2012 WL 1718825, at *12 (D. Ariz. Mar. 29, 2012) ("the majority of Dr. Parisian's report appears to state facts that could be directly presented to the jury and then make legal conclusions." "Because the Court finds Dr. Parisian's proffered testimony unhelpful to the trier of fact and unreliable, Defendant's Motion to Exclude her testimony is granted.") *In*

re: Rezulin Prod. Liab. Litig., 309 F. Supp. 2d 531, 555 (S.D.N.Y. 2004) (excluding expert testimony concerning the alleged downplaying of hepatotoxic effects of Rezulin in the published literature based on internal documents, memos, and e-mails, finding that the issues constituted "lay matters" and would amount to arguing from the witness stand).

Because Dr. Ritchie did not employ any specific engineering methods to support his opinion that Bard's testing was insufficient, he is doing nothing more than speculating as to what additional or different testing would have demonstrated; therefore, his opinion on Bard's testing is unreliable and will not assist the trier-of-fact in determining the issues.

D. Dr. Ritchie's Opinion on the SNF as a Safer Alternative Design Is Unreliable.

Bard stands by its assertion that Dr. Ritchie is neither qualified to offer an opinion on what the rates are in Bard retrievable filters or in SNF filters, nor has he employed any scientific methodology to support the opinion that the SNF is a safer alternative design as compared to Bard's retrievable filters.

The Plaintiffs take issue with Bard's point that the SNF, a permanent device, and Bard's retrievable filters are not functionally equivalent, calling it a "false dichotomy" because Bard's retrievable filters were first cleared as permanent devices. (Pls. Br. at 9:21-27.) The Plaintiffs ignore the fact that though the Recovery and G2 are retrievable filters that can be placed permanently, the SNF is a permanent filter that *cannot* be placed as a retrievable filter. They do not possess all of the same design characteristics; the design characteristics that make the Recovery and G2 retrievable are not present in the SNF and account for several of the functional differences between the products. While Bard filters were marketed as both permanent and retrievable filters, ignoring the retrievable function of these filters when arguing that the SNF is a safer alternative product is fatal to the reliability and helpfulness of Dr. Ritchie's opinions on this issue. As a product without the key feature of Bard's retrievable filters (retrievability), the SNF simply cannot be an alternative safer product; therefore, Dr. Ritchie's opinion on this

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

issue should be excluded. *See Casey v. Toyota Motor Eng'g & Mfg. N. Am., Inc.*, 770 F.3d 322, 331 (5th Cir. 2014) (proposed alternative design must not impair the product's utility); *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997) (rejecting proposed alternative design that lacked "functional element" present in allegedly defective product); *Mascarenas v. Cooper Tire & Rubber Co.*, 643 F. Supp. 2d 1363, 1369 (S.D. Ga. 2009) (proposed alternative design must be "equally efficacious"); *Clinton v. Brown & Williamson Holdings, Inc.*, 498 F. Supp. 2d 639, 645 (S.D.N.Y. 2007) (holding that the plaintiff's proffered alternative design must be the "functional equivalent" of the allegedly defective product); *Moss, by Gideon v. Wolohan Lumber Co.*, No. 92 C 7786, 1995 WL 348144, at *5 (N.D. Ill. June 7, 1995) (holding that proposed alternative design must exhibit same functions as allegedly defective product); *Felix v. Akzo Nobel Coatings*, 262 A.D.2d 447, 448, 692 N.Y.S.2d 413 (2d Dept. 1999) (rejecting proposed alternative design that was "not essentially the same" as the allegedly defective product because it exhibited "functional difference[s]").

The Plaintiffs essentially argue that because the SNF was the predicate device for (was "substantially equivalent to") the Recovery and G2 filters, that the Recovery and G2 have the same design characteristics as the SNF. That is incorrect. The Plaintiffs conflate the concepts of "substantial equivalence" under FDA regulations and the legal definition of an alternative safer design. These are separate concepts entirely. The Plaintiffs do not cite any cases to support the proposition that "substantial equivalence," as defined by FDA regulations and applied in the 510(k) process for product clearance, constitutes functionally equivalent alternative designs. The law contradicts their argument. *See, e.g.*, *In re Bair Hugger Forced Air Warming Devices Prod. Liab. Litig.*, No. MDL152666JNEFLN, 2017 WL 1373257, at *2 n.1 (D. Minn. Apr. 13, 2017) (acknowledging "[a]n FDA finding of substantial equivalence in the § 510(k) premarket approval process does not necessarily mean that the device under consideration has the same technological characteristics as the predicate device."); *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 505234, at *9 (S.D. W.Va.

Feb. 5, 2014) (holding "[w]hile 510(k) approval may mean the ProteGen was "substantially similar" to the TVT, it did not mean the products were identical. A new device may be 'substantially equivalent' even though its technology is very different from the predicate device"); *Runnels v. Tahsin Indus. Corp., USA*, No. 3:11-CV-106-CWR-LRA, 2013 WL 6834632, at *12 (S.D. Miss. Dec. 23, 2013) ("A feasible design alternative is a design that would have to a reasonable probability prevented the harm without impairing the utility, usefulness, practicality or desirability of the product to users or consumers.").

In further support of their argument against the exclusion of Dr. Ritchie's opinions that the SNF is an alternative safer product, the Plaintiffs refer the Court in their Response to Bard's Motion to Exclude Opinions of Dr. Robert McMeeking (Pls. Br. (Doc. 7806), at 14-21) where they attempt to distinguish the *Felix*[3] and *McCarthy*[4] opinions from the instant case. Both cases[5] stand for the proposition that "functional differences" between an allegedly defective product and the proffered alternative design are fatal to a Plaintiffs' case.[6] To avoid this result, Plaintiffs advocate for an overly narrow reading of the *Felix* and *McCarthy* holdings in an effort to limit the opinions' applicability only to cases where the alleged defect constitutes a functional aspect of the product. Plaintiffs' argument, however, ignores the reality – exemplified by the case at hand – that a product's allegedly defective design characteristics may be integral to – but not necessarily constitute – the

[3] *Felix v. Akzo Nobel Coatings, Inc.*, 262 A.D.2d 447, 692 N.Y.S.2d 413 (2d Dept. 1999).

[4] *McCarthy v. Olin Corp.*, 119 F.3d 148 (2d Cir. 1997).

[5] Both *Felix* and *McCarthy* interpret the law of New York which has a more developed body of law on this issue compared to the relative dearth of case law in the bellwether jurisdictions. However, at least one court in the bellwether jurisdiction of Wisconsin has considered and ruled on this issue. *See Below v. Yokohama Tire Corp.*, No. 15-CV-529-WMC, 2017 WL 679153, at *4 (W.D. Wis. Feb. 21, 2017) (concluding that plaintiffs offered insufficient evidence that high-speed tire – proposed as an alternative design – was sufficiently similar to light truck tire – which was allegedly defective).

[6] *See Felix v. Akzo Nobel Coatings*, 262 A.D.2d 447, 448, 692 N.Y.S.2d 413 (2d Dept. 1999) (rejecting proposed alternative design that was not essentially the same" as the allegedly defective product because it exhibited "functional difference[s]"); *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997) (rejecting proposed alternative design that lacked "functional element" present in allegedly defective product).

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

product's functionality. For example, in the case at hand, Plaintiffs have not alleged that retrievable filters are defective simply because they are retrievable. Rather, Plaintiffs argue that the filters' underlying design characteristics integral to their retrievable function may constitute the alleged product defects. Nevertheless, under *Felix* and *McCarthy*, the non-retrievable SNF filter lacks the retrievable function of the Recovery and G2 filters and this functional difference is fatal to Plaintiffs' use of the SNF filter as a proposed alternative design.

The Plaintiffs again note Dr. Ritchie's reliance on Dr. Betensky, this time, to support his safer alternative design opinion. Unfortunately, Dr. Betensky's analysis is unreliable in and of itself. As discussed in Section I, *supra*, Dr. Betensky merely calculated a "reporting risk ratio," ("RRR") which did nothing more than compare the proportions of anecdotal adverse events reports for the various retrievable filters over sales to the proportions of anecdotal adverse event reports for the SNF over SNF sales.[7] Dr. Betensky emphasized that "the qualifier 'reported' is important and that's indicating that the data are coming from reports, and are not being derived from a beautifully run and designed experiment like a clinical trial, in which there's perfect follow-up and in which it's really a true experiment. So the 'reporting' qualifier is there to say and to suggest that these are numbers that are reported. These are based on reports." (Ex. I, Betensky Austin Dep. Tr., 60:12-20.) Because of the inherent limitations in the data that she considered, Dr. Betensky described her RRR as a "crude estimate[] of risk." (*Id.* at 106:20-25.) Indeed, Dr. Betensky's RRR "could be an overestimate or it could be an underestimate" of risk. (*Id.* 62:14-19.) This undermines the reliability of Dr. Betensky's analysis and, in turn, Dr. Ritchie's reliance on it.

And, once again, expert opinions that rely on other expert opinions should only be admitted into evidence if the record shows that the "relying expert" independently evaluated the evidence supporting the other expert's opinion. *In re Toyota Motor Corp.*

[7] Bard refers the Court to Section I, p. 5, FN.1, *supra*, for a more complete discussion of the incomplete SNF data Dr. Betensky used in her analysis.

Unintended Acceleration Mktg. Sales Practices, and Prods. Liab. Litig., 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013). Dr. Ritchie did not independently verify Dr. Betensky's work" (Ex. A to Mot., Ritchie Dep. Tr., 139:16-140:18, June 9, 2017); therefore, Dr. Ritchie's opinion on the SNF as a safer alternative design is unreliable.

CONCLUSION

Because Dr. Ritchie is unqualified to opine about the topics identified above, failed to use scientific methodology, and/or simply relied on opinions and analyses of other experts without verifying those opinions, his opinions are unreliable, will not help the jury determine the issues, and should be excluded.

DATED this 18th day of October, 2017.

s/Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

James R. Condo (#005867)
Amanda Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
JCondo@swlaw.com
ASheridan@swlaw.com

Attorney for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that October 18, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000